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# Biotechnology Notes

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**Biotechnology Notes**, a compilation of agency activities, news events, and upcoming meetings, is prepared for members of the U.S. Department of Agriculture's (USDA) Committee on Biotechnology in Agriculture (CBA) by USDA's Office of Agricultural Biotechnology (OAB).

## INSIDE USDA

### BIOTECH COUNCIL TACKLES PUBLIC INFORMATION PLAN

Members of USDA's Biotechnology Council met September 19 to discuss several high priority issues including formulating a departmental plan for communicating biotechnology to the public. Some members suggested that such a plan should include communication training for those USDA scientists and policymakers who give media interviews. Others said funding of educational programs for young people should be part of the plan, as well as support for a national survey to determine public attitudes about agricultural biotechnology.

Other agenda items included a briefing by Council Chairman Alvin Young on the status of a government-wide research budget inventory effort and a request from the Commission of the European Communities to establish a memorandum of understanding with the Forest Service to develop a cooperative project on woody plant biotechnology.

In a roundup of agency news and events, the Economic Research Service said a new report entitled "Implications of New Technology for the Livestock Sector: Animal Growth Hormones" is now off press. To order a copy, please see page 6.

The Animal and Plant Health Inspection Service (APHIS), Biotechnology, Biologics and Environmental Protection (BBEP) Division, reported that 80 permits have been issued thus far for calendar year 1991, and that another nine are in the pipeline. According to Arnold Foudin, BBEP Deputy Director, Biotechnology Permit unit, the number of permits issued for this year alone is twice that of the three previous years. Foudin added that this trend will probably continue throughout 1992. To learn about other trends, forecasts, and projections, please call the Biotechnology Permit unit at 301-436-7612.

## **TWO NEW WORKSHOPS OFFERED**

USDA's Graduate School in Washington, DC is offering evening and weekend courses this fall in Foundations of Biotechnology and Fundamentals of Toxicology I. For details call 202-475-4280. The American Type Culture Collection, Rockville, MD is offering a workshop on the techniques and applications of recombinant DNA October 28-November 1 and November 4-8. A basic knowledge of nucleic acids is helpful but not necessary. Call 301-231-5566 for more details or FAX request to 301-770-1805.

## **MARK YOUR CALENDARS**

The Second International Symposium on the Biosafety Results of Field Tests of Genetically Modified Plants and Microorganisms will be held in Goslar, Germany, May 11-14, 1992. This symposium will focus on the latest worldwide biosafety results. For more details, please contact either Professor Dr. Rudolf Casper, Biologische Bundesanstalt, Institut fur Biochemie und Pflanzenvirologie, Messeweg 11/12, D-3300 Braunschweig at 0531-399401 (FAX: 0531-399239); or Martha Steinbock, USDA/OAB, Room 1001, RPE, 14th and Independence Ave., S.W., Washington, DC 20250-2200 at 703-235-4419 (FAX: 703-235-4429).

## **NEWS AROUND THE NATION (AND THE WORLD)**

### **TRANSGENIC GOATS PRODUCE HUMAN DRUG**

Researchers at the Tufts School of Veterinary Medicine, North Grafton, Mass., and the Genzyme Corp., Cambridge, Mass., have genetically modified goats to produce a human pharmaceutical, tPA (tissue plasminogen activator), in their milk. The drug is used to treat heart attacks.

The technology involves injecting DNA which encodes a foreign protein into the embryos of livestock. The embryos are transferred to a recipient mother for gestation. The resulting offspring, following gestation and breeding, secrete the new protein in their milk. The protein is then extracted and purified to make pharmaceuticals.

Research in which transgenic livestock are used to produce human pharmaceutical proteins is commonly referred to as transgenic pharming. It began a few years ago with mice and today the technology is also being applied to transgenic sheep, cattle,

rabbits. The advantages to transgenic pharming include an increased volume of proteins, low operating costs, and unlimited multiplication of the bioreactor.

## CANOLA FIELD TRIALS REQUESTED

Ameri-Can Pedigreed Seed Company, a subsidiary of Calgene Inc., Davis, CA, has asked APHIS, Biotechnology, Biologics and Environmental Protection Division, to approve field trials of genetically modified canola. According to Calgene, the varieties to be tested have been modified to produce a novel oil with increased levels of stearic acid, making them suitable for margarine and confectionery products. If approved, the trials would take place next month at three sites in southern Georgia.

Canola is a type of rapeseed and is the world's third largest oilseed crop. For more information, call either Dan Wagster at Calgene Inc. (916-753-6313) or Eric Rey at Ameri-Can Pedigreed Seed Co. (901-753-0080)..

## PROMOTION VS. EDUCATION: WALKING A THIN LINE

The Food and Drug Administration (FDA) is using its regulatory authority to clamp down on drug companies that promote products or uses for products that have not been approved by the FDA and on companies that are not truthful or balanced in their promotion of products or uses that have been approved by FDA. At this time the concern about unacceptable promotional practices only applies to drugs and biological products.

Tied to the issue of illegal promotion is the matter of scientific exchange of data. While independent scientists may talk about their discoveries of as yet unapproved products, the FDA regulations prohibit firms from doing so, even though the same firms often sponsor the studies and fund most of the scientific and medical education programs. The question for FDA, therefore, is how to give scientists as much freedom of expression as possible to talk about their research while at the same time enforcing the prohibition against manufacturers promoting unapproved products or exaggerating the benefits of those that have been approved.

To help determine whether a program is promotional or educational, the FDA says the critical criterion should be independence. In other words, did the sponsor help to select topics or speakers? Is the organization that actually produces the program too dependent on one sponsor? Is the identity of the funding sponsor masked from the audience?

These and other issues will be explored more closely in an FDA draft discussion paper to be released for public comment in several

weeks. For further information, please call James Morrison, Acting Director of FDA's Office of Drug Standards, at 301-443-8017, or the FDA's Division of Marketing, Advertising and Communications at 301-227-6824.

#### **DOING BIOTECH IN GUATEMALA**

The Guatemalan government has developed a national biotechnology program that covers research and education in both public and private sectors, according to the July/August 1991 issue of *AgBiotechnology News*. Thirty biotech research projects, mainly in agriculture, are currently underway. For more information write to E. O. Franco, Facultad de Agronomia, Universidad de San Carlos, Apartado Postal 1545, Guatemala City, Guatemala.

#### **HOW TO TEACH BIOTECHNOLOGY**

Over 100 scientists and teachers will meet in Madison, Wisconsin, October 28-30 at the National Biotechnology Education Sharing Conference to develop guidelines for teaching biotechnology, to examine teacher training opportunities, and to discuss models for school-business partnerships. The recommendations and guidelines will help teachers nationwide to establish or improve upon biotech education programs in their schools and colleges.

The conference is funded by the National Science Foundation with additional support from the Center for Biology Education of the University of Wisconsin-Madison. The proceedings will be made available in journals and through the National Science Foundation. For more information or to register to attend, please call 1-800-442-4617.

#### **EPA ADVISORY COMMITTEE MEETS**

The Environmental Protection Agency's (EPA) Biotechnology Science Advisory Committee met September 30 in Alexandria, VA. to discuss a number of issues. Foremost on the agenda were reports from various subcommittees that met during 1990 through July 1991. These reports covered mobile genetic elements, ecoregions, good developmental practices, implementation of scope principles under EPA statutes, and the proposed biotechnology rule. Minutes of the meeting are being prepared and may be ordered by calling 202-260-6900.

#### **NATIONAL ADVISORY BOARD MEETS**

The National Institutes of Health (NIH)'s National Biotechnology Policy Board held two public hearings last month -- one in San

Francisco and the other in Washington, DC -- to gather information on the principal problems facing the biotechnology effort in this country. Among the presenters at the Washington, DC meeting was Richard Godown, president of the Industrial Biotechnology Association. Godown said the principal concern facing the biotechnology industry is resolution of the scope document. He said industry feels enough time has gone by and the issue of scope needs to be resolved.

The National Biotechnology Policy Board is made up of representatives from both the private and public sector. Members review and appraise the Federal government's biotechnology programs, as well as some private sector activities, and pass along their recommendations to the Congress and the President.

Some of the subject areas the Board may review include policies that enhance research, competitiveness, technology transfer, training of scientists, cooperative research initiatives, and regulatory policies. To learn more about the testimony given at the Washington, DC public hearing, or about the role of the Board, please contact Becky Lawson at 301-496-9838 or send a FAX to 301-496-9839.

### **IN CASE YOU WEREN'T THERE**

■ Many of our most important forage crops share the same center of origin in South America: Uruguay. Recognized as one of the germplasm capitals of the world, Montevideo, Uruguay is also where the **Second International Symposium on Science and Technology as Productive Forces** was held in early September.

Invited keynoter Alvin Young, OAB Director, spoke on "Agricultural Biotechnology: Opportunities and Challenges." He discussed important new developments in agricultural biotechnology as well as several sets of challenges. International exchange of data and information about the fundamental research is crucial to biotechnology, said Young. He also emphasized the need to train more young men and women in science. He also stressed the need to better conserve and use plant and animal genetic resources and for scientists worldwide to do a better job of communicating biotechnology to the general public.

■ **Federal Technology Transfer** was the topic at the September 10 meeting of the local chapter of the Association of Biotechnology Companies. Representatives from the Department of Energy (DOE), the NIH, the FDA, and the USDA explained how each agency manages technology transfer projects. The DOE spokesman said technology transfer is "an explicit mission of all of the DOE laboratories" and that it is primarily a person-to-person rather than a company-

to- company transfer. The USDA representative said more than 200 cooperative agreements have been signed in the last 5 years and the emphasis is on solving agricultural problems. The NIH said tech transfer is handled through licensing of inventions and cooperative research and development agreements, commonly referred to as CRADA's.

## NEW PUBLICATIONS

- "Final Consensus Report: Global Initiative for the Security and Sustainable Use of Plant Genetic Resources." A report prepared by the Keystone Center based on a meeting held in Oslo, Norway, June 1991. To request a copy, please call 303-468-5822 or FAX request to 303-262-0152.
- "Technologies Available for Licensing." Prepared by the University of Florida's Biotechnology Institute. April 1991. To order a copy, either call 904-462-3904 or FAX your request to 904-462-5261.
- A new bibliographic reference work entitled "Biotechnology: Public Perceptions" is now available from the National Agricultural Library. To receive a copy call 301-344-3340 or FAX request to 301-344-5472.
- *Bioconnection* is a publication of the Michigan Biotechnology Institute. The summer 1991 issue is devoted to the proceedings of the Midwest Industrial Users Conference held in East Lansing, MI, May 30-31. The topic was "Agricultural Resources in Industry: Biotech Business and Product Opportunities. To receive a copy please call 517-337-3181.
- "Biotech '92: Promise to Reality." An industry annual report prepared by Ernst & Young. 1991. To order a copy write to Ernst & Young, One Sansome St., San Francisco, CA 94104.
- "Implications of New Technology for the Livestock Sector: Animal Growth Hormones." Prepared by USDA's Economic Research Service. Agriculture Information Bulletin Number 626. September 1991. To order one copy at \$4.00 please call 1-800-999-6779 or write to ERS-NASS, P.O. Box 1608, Rockville, MD 20849-1608.
- *Cassava and Biotechnology*. Proceedings of a workshop held in The Hague, The Netherlands, March 21-23, 1990. To receive a copy call 31-70-3485412 or FAX order to 31-70-3484848.
- *Plant Growth Regulators*. Published by Agrow. Surrey, England. July 1991. \$420. To order call 081-948-3262 or FAX request to 081-948-5598.

■ *Microbiological Ecology: Principles, Methods and Applications.* Edited by M. Levin, R. Seidler, M. Rogul. 1991. McGraw Hill Inc. To order a copy write to McGraw Hill Inc., 1221 Avenue of the Americas, New York, NY 10020.

## UPCOMING MEETINGS

Oct. 9-10: Workshop to Identify and Examine Issues Associated with Assessing the Risks Associated with Large-Scale Environmental Applications of Engineered Microbes for Agricultural or Biotreatment Purposes. Sponsored by the Maryland Biotechnology Institute. Call 301-455-3763 for registration information. The FAX number is 301-455-1077.

Oct. 13-16: International Marine Biotechnology Conference. Baltimore, MD. Call 703-941-5373 or 415-524-2460.

Oct. 15: "University Technology Transfer" is the topic at this month's meeting of the local chapter of the Association of Biotechnology Companies. Washington, DC. To make a reservation, please call 202-234-3330 or FAX request to 202-234-3565.

Oct. 15: A symposium on analysis of plant and animal genomes. Cornell University. For details call 607-255-2300.

Oct. 16-18: European Biotech Partnering Event. The Hague, The Netherlands. Call 31-0-70-3286666 or FAX inquiry to 31-0-7-3242075.

Oct. 17: "How to Coordinate Regulatory Approvals: Strategies for Patent, FDA, and HCFA Reimbursement/Standards. Gaithersburg, MD. Sponsored by the Montgomery County, Maryland High Technology Council Inc. To register call 301-762-6325 by October 14.

Oct. 21-23: Fourth International Symposium on Biotechnology and Plant Protection. University of Maryland, College Park, MD. Jointly sponsored by the University of Maryland, USDA, and the Monsanto Agricultural Company. The focus will be bacterial pathogenesis and disease resistance of plants. Attendance is limited to the first 200 people who register. For further information, please call either 301-405-1582 or 301-344-3338.

Oct. 22-24: 7th International Congress and Exhibition for Biotechnology. Sponsored by BIOTECHNICA Hannover. Hannover, Germany. For more details call Jeff Gwaltney at 202-377-3090.

Oct. 24: Food Safety Workshop for Journalists. Columbia, SC. Call 803-656-3876 for more details.

Oct. 25-26: Biosciences and Information. Computer Applications in the Biosciences. Braunschweig, Germany. Write to GBF, Mascheroder Weg 1, W-3300 Braunschweig-Stockheim, Germany.

Oct. 30-31: Meeting of USDA's Agricultural Biotechnology Research Advisory Committee's Working Group on Classification and Confinement. Washington, DC. Call 703-235-4419.

Nov. 6-9: A Symposium on Minority Participation in Forestry and Forestry-Related Sciences: A Need, A Goal, A Commitment. Huntsville, Ala. Sponsored by USDA's Forest Service, CSRS, Extension Service, Alabama A&M, and Tuskegee University. Call Jim Reaves at 205-851-5410. The FAX number is 205-852-4061.

Nov. 7-8: International Conference on Biotechnology, Biological Frontiers and Biochemistry. New Dehli, India. For details please write to V. M. Bhatnagar, Alena Chemicals of Canada, P.O. Box 1779, Cornwall, Ontario K6H 5V7, Canada.

Nov. 14-15: 4th Annual U.S. Public Health Service Technology Transfer Forum. Sponsored by NIH. Bethesda, MD. Call Laura Kurie for details at 301-986-4870. The FAX number is 301-913-0351.

Nov. 20-22: "Bioinformatics in the 90's." Maastricht, The Netherlands. This conference focuses on the use of computer and information technology in biology. For more information write to Bioinformatics Secretariat, Mrs. G. v.d. Linden, Bernhardstraat 33, 7491 EA Delden, The Netherlands; or call 054-07-63716.

Nov. 25-29: Somatic Cell Genetics is the title of a workshop being held this date in Dehra Dun, India. It is sponsored by the International Union of Forestry Research Organizations Working Group on Somatic Cell Genetics. The workshop focuses on current research and development in forest biotechnology and tissue culture. For more details call Stan Krugman at 202-453-9552.

Biotechnology Notes is written by Marti Asner, public affairs specialist in USDA's Office of Agricultural Biotechnology. Suggestions for items to include in future issues are always appreciated and may be sent to USDA/OAB, Room 1001, Rosslyn Plaza East, 14th and Independence Ave., S.W., Washington, DC 20250-2200; or call the OAB at 703-235-4419. The OAB FAX number is 703-235-4429.